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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,492	04/01/2004	Joshua D. Rabinowitz	00024.03CON	8599

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EXAMINER	
HAGHIGHATIAN, MINA	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 12/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/816,492	RABINOWITZ ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/24/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 9 are vague and indefinite for reciting the statement "by the patient of the formation of, and delivery of, the condensation aerosol". It is not clear what "of the formation of" means. It is also believed that the term "and delivery of" is redundant since administration by inhalation is "delivery". Remaining claims are rejected for depending on a rejected base claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6, 9, 11-12 and 13-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartus et al (6,514,482) in view of Staniforth et al (20010020147 A1) and further in view of Faithfull et al (6,041,777).

Bartus teaches a method of pulmonary delivery of a medicament, which includes administering to the pulmonary system and in particular to the alveoli or the deep lung particles comprising an effective amount of a medicament, where the particles preferably have an aerodynamic diameter between about 1 and about 5 μm. Particles can consist of the medicament or can further include one or more additional components. Rapid release of the medicament into blood stream and its delivery to its site of action (col. 3, lines 41-59).

Bartus discloses that medicaments which can be used in the said method include stimulants, appetite suppression, etc (col. 7 lines 15-35).

In a preferred embodiment, Bartus discloses that particles are delivered from an inhalation device, preferably they are administered via a dry powder inhaler (DPI), metered dose inhaler (MDI), nebulizers or instillation techniques. Various suitable devices and methods of inhalation which can be used are known in the art (col. 7, line 24 to col. 8, line 8).

Bartus discloses that at least 50% of the mass of the particles stored in the inhaler receptacle is delivered to a subject's respiratory system in a single breath activated step. Amounts of drug or medicament present in the particles can range from 1 to about 90 weight percent (col. 8, lines 26-41). Bartus lacks specific disclosure on ephedrine or fenfluramine.

Staniforth teaches delivery of a drug comprising a multiple unit dosing device. The particles of the formulations comprise at least about 80% drug, and preferably at

least about 90% drug (see [035]). Suitable drugs for the said formulation include ephedrine (see [0126]). The formulations can be delivered to the lung via inhalation (see [0041]). Staniforth and Bartus lack teachings on producing condensation aerosol and also lack specific disclosure on the presence of less than 5% degradation products.

Faithfull teaches methods and apparatus for closed-circuit ventilation therapy. In procedures involving liquid ventilation, this treatment and recirculation of the exhaled gases, vapors or liquids substantially reduces the amount of respiratory promoter needed to provide effective ventilation (col. 10, lines 13-26). Faithfull discloses that the nebulizer is used to provide fluorochemicals, heated above body temperature, to the ventilating gas in the form of a vapor. This may be accomplished by spraying or contacting a wetted surface or wick with the gas to form droplets. The fluorochemical liquid medium is particularly well dispersed in the lungs. As the fluorochemical vapor cools in the body it is deposited on the pulmonary surfaces (col. 16, lines 44-67).

Faithfull also discloses that the said method provides for the independent delivery of pharmaceutical agents or their use in conjunction with other vapors (col. 25, lines 15-30).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the method of delivering a medicament to a patient's respiratory tract of Bartus, by adding the specific stimulants of Staniforth and the steps of heating the composition and having patient inhale the condensates,

because of the disclosed benefits of such a method, including minimized trauma to the lungs and a better resolution of pulmonary and systemic disorders, as taught by Faithfull. Furthermore one of ordinary skill in the art would know that condensates have a high percentage of purity of the drug and less degradation products. Also noted that optimization of concentration ranges will not support patentability. Additionally, kits, including instructions are obvious and known to one of ordinary skill in the art.

Claims 1, 6, 9, 11-12 and 13-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartus et al (6,514,482) in view of Staniforth et al (20010020147 A1) and further in view of Byron et al (20040016427 A1).

Bartus and Staniforth, discussed above, lack disclosure on condensation aerosols and the devices for producing condensates involved in the method of therapy.

Byron et al disclose a method and apparatus for generating an aerosol. The aerosol is formed by supplying a material in liquid form to a tube and heating the tube such that the material volatizes and expands out of an open end of the tube. The volatized material combines with ambient air such that volatized material condenses to form the aerosol (see abstract and [0012]). The aerosols intended for inhalation typically have a mass median particle diameter of less than 2 microns (see [0074]).

Byron et al disclose that the apparatus may be fairly large or may be miniaturized to be hand held (see [0086]).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have implemented the aerosol device article of Byron et al for delivering the aerosolized composition of Bartus and the specific stimulants of Staniforth to a subject's respiratory tract because it would be desirable to provide an aerosol delivery article which is capable of producing condensate aerosol particles of relatively small size without the necessity of subjecting the material to be aerosolized to exposure to a significant degree of heat or high temperatures. Also noted that optimization of concentration ranges will not support patentability. Additionally, kits, including instructions are obvious and known to one of ordinary skill in the art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,780,399

B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are either anticipated by, or would have been obvious over, the reference claims. Here claims 13-23 are generic to all that is recited in claims of U.S. Patent No. 6,780, 399 B2. That is, claims of U.S. Patent No. 6,780, 399 B2 fall entirely within the scope of claims 13-23, or in other words, claims 13-23 are anticipated by claims of U.S. Patent No. 6,784, 399 B2. Specifically, the method of administering of instant claims 13 and 14 are obvious over compositions for delivery of claim 1 of the reference claims and the kit recited in instant claims 15-23 is anticipated by the compositions and method of producing the compositions as recited in claims of U.S. Patent No. 6,780, 399 B2.

Claims 13-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/815, 527. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are either anticipated by, or would have been obvious over, the reference claims. Here claims 13-23 are generic to all that is recited in claims of copending Application No. 10/815, 527. That is, claims of copending Application No. 10/815, 527 fall entirely within the scope of claims 13-23, or in other words, claims 13-23 are anticipated by claims of copending Application No. 10/815, 527. Specifically, the method of administering of instant claims 13 and 14 are obvious over compositions for delivery of claim 1 of the reference claims and the kit recited in instant claims 15-23 is anticipated by the compositions and method

of producing the compositions as recited in claims of copending Application No. 10/815,527.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 13-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/150,268. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are either anticipated by, or would have been obvious over, the reference claims. Here claims 13-23 are generic to all that is recited in claims of copending Application No. 10/150,268. That is, claims of copending Application No. 10/150,268 fall entirely within the scope of claims 13-23, or in other words, claims 13-23 are anticipated by claims of copending Application No. 10/150,268. Specifically, the method of administering of instant claims 13 and 14 are obvious over method of administering of claim 15. The time for achieving peak plasma is disclosed in the specification of the reference application and also is an inherent property of the formulation. The kit recited in instant claims 15-23 is anticipated by the compositions and method of producing the compositions as recited in claims of copending Application No. 10/150,268. Application No. 10/150,268 has been allowed but not yet published.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mina Haghighatian
December 06, 2004

MICHAEL G. HARTLEY
PRIMARY EXAMINER